UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ELI LILLY AND COMPANY, Plaintiff, v. ACTAVIS ELIZABETH LLC, GLENMARK PHARMACEUTICALS INC., USA, SUN PHARMACEUTICAL INDUSTRIES LIMITED, SANDOZ INC., MYLAN PHARMACEUTICALS INC., APOTEX INC., AUROBINDO PHARMA LTD., TEVA PHARMACEUTICALS USA, INC., SYNTHON LABORATORIES, INC., ZYDUS PHARMACEUTICALS, USA, INC. Defendants.	)	Civil Action No. 07-3770 (DMC) (JAD) **REDACTED - PUBLIC VERSION**

DECLARATION OF HARRY C. BOGHIGIAN

I, Harry C. Boghigian, declare and state as follows:

1. My name is Harry C. Boghigian. I am submitting this declaration on behalf, and in support, of Mylan's opposition to Lilly's motion for (1) deferral of entry of judgment or for an order to show cause with temporary restraints and (2) a temporary restraining order.

I. Background and Qualifications.

2. I am a pharmaceutical executive with over thirty-nine years of domestic and international experience in the commercialization and marketing of pharmaceutical products.

3. I have a Bachelor of Science Degree from the University of New Hampshire Whittermore School Of Business and have attended a number of Executive Business Programs at several of Europe's leading business schools such as INSEAD Institute of Business

Administration in Fontainebleau Cedex, France, and IMD Business School in Lausanne Switzerland.

4. My career in the pharmaceutical industry began in 1971 as a sales representative at Hoffmann-La Roche, one of the top ten global brand-name pharmaceutical research and development companies. During my career at Hoffmann-La Roche, I held numerous positions of increasing responsibility in the U.S., and internationally involving business development, market research, marketing, brand management, sales, sales management, strategic planning, portfolio management and product commercialization.

5. While at Hoffmann-La Roche, I was involved with over forty products in various stages of development and commercialization. My experience includes management of a number of very successful co-promotion arrangements including Zantac™, the first co-promotion arrangement in the history of the industry. This product, as a result of the co-promotion arrangement, became one of the world's most widely prescribed products for the treatment of ulcers and reflux disease. Today, it continues to be a recognized brand and is widely advertised as an over-the-counter product for gastric reflux disease.

6. My positions of responsibility at Hoffmann-LaRoche included Vice President of Business Operations, where I was responsible for approximately 60% of U.S. revenues and an operating budget of $130 million. I was also appointed Vice President of U.S. Marketing with responsibility for a $2.3 billion portfolio of products, and a product marketing budget in excess of $343 million, where I led a team of marketing professionals that increased revenue 20% annually. My international experience included positions as Global Business Director for several marketed and development compounds, and Senior Vice President and General Manager of the Canadian division of Hoffmann-La Roche. My responsibility as a Global Business Director was

to coordinate the marketing for new product introductions and currently marketed products in the US, France, Germany, Italy, UK and Japan. As Senior Vice President and General Manager for the Canadian division, I was responsible for reorganizing and growing the Canadian division three-fold. I restructured the organization, launched three new products and increased sales of currently marketed products.

7. I co-founded PBN PHARMA LLC, a Chicago-based research and development healthcare company in 2003. The company owns twelve patents and is focused on the development, licensing and commercialization of prescription and over-the-counter products.

8. In 2001, I founded Pharma Consultants LLC, a New Jersey-based consulting firm serving start-up, small to medium size healthcare companies and advertising agencies in all areas of pharmaceutical sales and marketing.

II. Discussion and Opinions.

9. Based upon my extensive experience and knowledge of the pharmaceutical industry, and review of materials relevant to this case, I wholly disagree with Lilly's assertions of alleged "irreparable harm," none of which withstand scrutiny for any number of reasons. I address just some of these reasons below.

10. First, in my view, Lilly has not identified, much less proven, any actual "irreparable harm" that it might suffer from the defendants' launch of any generic presentation(s) of atomoxetine. In fact, the purported harm that Lilly alleges is either not real harm at all when the actual facts are considered, or is entirely unfounded and speculative. Either way, it is not (and cannot be), in my view, "irreparable" in any sense of that term.

11. Second, even if Lilly's list of purported "harms" could be considered real harm amounting to irreparable harm, the potential damages, if any, from the defendants' launch of

their generic presentation(s) of the atomoxetine product are entirely quantifiable, should the appellate court ultimately find that they infringe a valid and enforceable claim of the asserted '590 patent. That is, the "harms" that Lilly identifies can be adequately remedied by money damages in the event that the defendants ultimately are found to infringe a valid and enforceable claim of the asserted patent.[1]

12. In forming the opinions and conclusions set forth in this declaration, I considered and relied upon my education, background, and thirty-nine years of experience in the pharmaceutical industry. I also reviewed and considered the documents cited or listed as part of this declaration, including Lilly's papers, the exhibits thereto, and the declarations of Michael Mason and Raymond S. Sims.

A. Lilly Has Not Identified, Much Less Proven, Any Actual "Irreparable Harm" That It Would Suffer From The Launch Of Generic Atomoxetine Products.

13. As an initial matter, the glaring omissions in Lilly's papers, including the Mason and Sims declarations, are troubling. These omissions alone demonstrate that Lilly will not, and indeed cannot, suffer any truly "irreparable harm" from the launch of generic atomoxetine products.

14. First, as Lilly and its declarants conveniently neglect to mention, this is not a situation where Lilly would (or even could) suffer serious financial harm, even if all of the alleged "harms" Lilly concocts come to pass. And it is certainly not a situation where any damages that may occur would seriously harm or otherwise impact Lilly's business, much less damage it so severely that it could not be made whole. The reasons for this are simple and

[1] By addressing Lilly's alleged "harms," I am not suggesting that I agree that if found to infringe a valid and enforceable claim of the patent, the defendants should be held responsible for any such "harms."

straightforward, and surprisingly found nowhere in Lilly's papers: Strattera accounts for precious little of Lilly's revenues.

15. As set forth in Lilly's 2009 Annual Report, Lilly generated annual revenues in excess of $21.8 billion (with an increase in total sales of 7% over the prior year).[2] ***Of that total, U.S. sales of Strattera made up barely over 2% of Lilly's revenues.*** Strattera did not even make Lilly's top ten list of products.[3] Nor did Lilly identify Strattera as a "key contributor" to 2009 revenue growth.[4] Rather, Lilly identified a number of other products, including five with annual sales exceeding $1 billion dollars (Zyprexa, Cymbalta, Humalog, Alimta and Cialis) generating in excess of $13 billion in worldwide sales, as the top-selling brands and key contributors—again, none of which included Strattera.[5] While Lilly does list Strattera sales, it is by far the smallest contributor to worldwide sales of the group listed on page 21 of Lilly's 2009 Annual Report.

16. Lilly also posted net revenue of $11.234 billion for the first half of 2010, an increase of 9% over the same period last year.[6] But again, Strattera was not identified as a key contributor to this growth. Nor could it since, as discussed further below, Strattera prescriptions have continued to decline every year.

17. In addition, in the first quarter of 2010, it bears noting that Lilly signed an agreement to acquire Alnara Pharmaceuticals, Inc.; entered a licensing agreement with Marcadia Biotech, Inc.; launched a new product, Livalo; and entered into a new partnership with Walmart

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[2] Lilly 2009 Annual Report at 21, Spataro Decl. Ex. 5.
[3] *See id.* at 21 (listing Strattera at number 11).
[4] *See id.*, Shareholders Ltr. at 4.
[5] *See id.*, Shareholders Ltr. at 2-4; *see also id.* at 21.
[6] *See* Lilly Press Release, Second Quarter Results, July 22, 2010, Spataro Decl. Ex. 4.

to provide a co-branded insulin product.[7] Lilly also posted cash and cash equivalents in 2009 of $4.46 billion.[8] This is certainly not the picture of a company in financial crisis or concerned with its future cash flow due to the loss of Strattera sales.

18. On top of that, even after the Court's decision in this matter, Lilly publicly announced that:[9]

- The "court decision will not cause the company to modify its current 2010 earnings per share guidance"; and
- "[W]e still expect to generate sufficient cash flow in the coming years to fund research and development, make necessary capital investments and to pursue anticipated business development opportunities."

So even according to Lilly, the potential loss of Strattera was not even significant enough to change its earnings guidance, or deviate from any of its current business plans. In other words, it is business as usual for Lilly. It is not by any means irreparable.

19. All told, Lilly cannot, in my view, seriously claim, much less establish, irreparable harm from the loss of patent protection for a product that accounts for barely 2% of Lilly's revenues; that admittedly is not a key contributor to Lilly's growth or business; and that does not even merit a change in the earnings guidance or other business plans. Far from it in fact – this is a textbook example of normal financial losses that are not, and cannot be, considered irreparable to a company of Lilly's size. Again, Lilly and its declarants do not even bother to address this significant point.

20. REDACTED

REDACTED The fact that Lilly has not even changed its earnings guidance alone suggests that it is not. Moreover, as fully

[7] *Id.*
[8] Lilly 2009 Annual Report at 36, Spataro Decl. Ex. 5.
[9] *See* Lilly Press Release, August 12, 2010, Spataro Decl. Ex. 2.

explained in my expert report dated February 20, 2009 (the contents of which are incorporated herein by reference),

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21. Once again, Lilly cannot even begin to establish irreparable harm from the potential loss of revenues attributable to a product like Strattera that not only barely exceeds 2% of company revenues, but is not even profitable.

22. For at least these reasons alone, Lilly's entire irreparable harm analysis falls apart.

B. Lilly's Supposed "Harm" Is Entirely Quantifiable And Fully Compensable By Money Damages.

23. Even if that were not enough, the "harm" that Lilly allegedly will suffer as a result of the launch of competing generic products is, without doubt or question, quantifiable and fully compensable by money damages. Nothing Lilly or its declarants have said, or could say, can change this fact.

1. Any Alleged Harm Stemming Or Otherwise Resulting From Lost Sales, Lost Market Share, Lost Revenue, And/Or Lower Prices Is Fully Quantifiable And Compensable By Money Damages.

24. In the end, Lilly's "harms" come down to lost sales, lost market share, lost revenue, and/or lower prices, which can be quantified.

25. Lilly argues that, through any number of scenarios, and for any number of reasons, a generic launch by the defendants will result in lost Strattera sales to the defendants, which in turn will lead to lost market share, lost revenues and lower prices. While I disagree with Lilly's assessment of the impact of lost sales, the fact is that the impact of those lost sales

can be quantified and calculated no matter how or why they occur. Lilly and its declarants do not even attempt to prove otherwise.

26. Lilly's efforts to provide examples of products that were "harmed" by generic competition further reinforces my point that the harm in this situation is lost sales and market share, both of which can be readily calculated. Lilly argues that certain products lost market share due to competitors entering the market. For example, Lilly's expert, Sims, cites Pravachol and Zoloft, which faced generic entry in April and August 2006 respectively, and which purportedly lost approximately 80 percent of their prescriptions to generics within three weeks of generic entry. Similarly, Sims cites Allegra, which faced generic entry in September 2005, and purportedly lost approximately 80 percent of its prescriptions to the generic entry after five weeks.[10] These examples serve only to reinforce my point that lost sales and lost market share can be calculated, and thus Lilly's damages would not be irreparable, but fully compensable by money.

27. With respect to margins, pricing and managed care, Lilly argues that for any number of reasons, it would be severely impacted and that the launch of a generic would accelerate physician prescribing toward the generic.

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Even if Lilly's speculation came to fruition (and Lilly provides no evidence that it would), and even if Lilly could prove that this is a harm for which the defendants should compensate it, REDACTED (whether to institutional customers or managed care customers) is monetary harm that could be easily and readily calculated.

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[10] *See, e.g.*, Sims Decl. ¶ 18.
[11] *See, e.g.*, Sims Decl. ¶ 17.

28. Furthermore, not only would "harm" to Lilly be easily quantifiable, but Lilly would have already created estimates and forecasts estimating the impact of generics. Recognizing that several generic companies filed a paragraph IV ANDA and that there was a chance Lilly would lose the case, Lilly would have estimated the generic impact if one or more companies introduced a generic product. Lilly would have calculated the decline based on the current declining prescription trend of Strattera.

29. It is also likely Lilly would continue to support and promote the product until the court decision is final. Lilly's continued promotional support and message to physicians and pharmacists is that the Strattera decision will be appealed and that Lilly believes that appeal will ultimately result in a reversal of the Court's decision.[12] Even if the continued promotion does not slow erosion, the damages would be quantifiable.

30. Based on Lilly's own press release, while they are disappointed with the Court's decision, they "remain confident in our ability to execute on our strategy and in our long-term business prospects."[13] While they will appeal the court's decision, they will continue their plan of lowering their cost structure "by at least $1 billion by the end of 2011 and reducing [their] full-time workforce."[14] Lilly has already been reducing costs for the last couple of years recognizing a shortfall in product revenues. As Lilly's own press releases make clear, none of it has anything to do with Strattera.

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[12] Lilly Press Release, August 12, 2010, Spataro Decl. Ex. 2.
[13] *Id.*
[14] *Id.*

2. Lilly Grossly Exaggerates The Purported Extent Of Its Alleged Harm, Which Can Be Adequately And Fully Compensated By Money Damages.

31. Lilly grossly exaggerates the extent and nature of its alleged harm. For example, Lilly asserts that Strattera is a "top selling drug for the treatment of ADHD."[15]

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This is certainly not the position of a "top selling product."

32. Lilly is not in such a unique position that it would suffer more harm than another drug manufacturer facing the launch of a competing prescription product, or any other patentee facing competition for that matter. And while I believe that Lilly exaggerates the extent of its alleged harm, even if the harm Lilly alleges does, in fact, occur, that harm would be monetary and redressible by a damages award (assuming of course that Lilly could adequately demonstrate that the defendants should be held accountable for such alleged "harm").

REDACTED

In my opinion and experience, this is not the case.

34. As an initial matter, lost market share and price erosion, no matter when or how they occur, are the epitome of quantifiable money damages.

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[15] Mason Decl. ¶ 11.
[16] *See, e.g.*, Sims Decl. ¶¶ 19-22.

35. In fact, the actual evidence, including the examples cited by Lilly, proves just the opposite – that there is nothing irreparable about the harm Lilly alleges. One example of a company that lost and won back its customers is Tylenol. In the fall of 1982, several bottles of Tylenol product were poisoned, resulting in several deaths. As a result, Tylenol's share of the $1.2 billion market dropped from 35% to 7-8%. Tylenol was Johnson & Johnson's most profitable product. The industry perspective was that Johnson & Johnson would never be able to regain its position in the market; obviously they were wrong. As a result of public relations, advertising, and marketing Johnson & Johnson was able to regain over 80% of its customers by the fall of 1983 and continue to be a dominate product in the OTC pain market.[17]

36. Even the examples cited by Lilly contradict Lilly's own contentions here. For instance, Plavix (clopidogrel), one of the world's best selling drugs with some $6 billion in annual sales, was threatened with an unauthorized generic introduction. A generic drug manufacturer purportedly began "flooding" the market with generic product in July 2006, and within days, more than 60% of Plavix prescriptions were being filled with the generic, priced up to 20% lower than the brand-name product. The generic company had shipped quantities that industry experts expected would last until 2007. The court then halted continued sales of the generic. With its exclusivity restored, Plavix not only rebounded in 2007 to reclaim the number two position in the world, Plavix revenues actually increased by 28% (to levels greater than prior to generic entry). As a result of advertising and marketing, Plavix continued to enjoy significant

[17] *Tylenol's 'Miracle' Comeback,* www.time.com (Nov. 17, 1983); *The Tylenol Crisis: How Effective Public Relations Saved Johnson & Johnson*, aerobiologicalengineering.com; *Johnson & Johnson's Tylenol Scare*, iml.jou.ulf.edu.

sales. As outlined in this case, the lost sales were not only recovered by the brand product after the injunction, but sales actually increased. And in the end, they were all easily quantified.[18]

3. Lilly's Harm Arguments Are Also Based On The Flawed Assumption That Atomoxetine Sales Can Be Tied To The Invalid '590 Patent, Rather Than External Stimuli Like Promotion And Advertising.

37. Lilly's harm arguments also fail (and indeed make no sense) for the simple reason that the financial success, if any, of Strattera has nothing to do with the invalid '590 patent. Rather, for the reasons discussed in my prior expert report and during my trial testimony, there is no nexus between the '590 patent and Strattera's sales.

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38. REDACTED

Indeed, Strattera continues to report lower sales only to be offset by continued pricing actions needed to offset prescription declines.[19] This, in turn, means that fewer and fewer physicians feel the product offers any significant features over the market leaders, which confirms Lilly's prior statement that "doctors will not prescribe it" if it does not meet their clinical needs and/or patients do not feel it works. The decline in prescriptions has continued through the first quarter of 2010 as documented in the IMS prescription audit for the period

[18] It is difficult to understand why Lilly and its declarants cite the Protonix situation. To my knowledge, there was no injunction entered in that case, and to date, the generic has not been pulled from the market.

[19] Lilly Press Release, Second Quarter Results, July 22, 2010, Spataro Decl. Ex. 4. Sales in the second quarter in the U.S. were only $100.4 million, a US decrease of 5% offset by higher net effective selling prices. *Id.*

September 2008-March 2010. Again, this is just more evidence that the product has not been a commercial success.

39. Significantly, however, it is the marketing, advertising and pricing actions that are creating the sales, and not anything related to the invalid '590 patent. As outlined in Lilly's own documents, physicians have not recognized any clinically differentiating features that demonstrate any superiority over the stimulants. As a result, it is clear from the prescription data and Lilly's market research that sales are the result of promotion and that physicians' usage in spite of the promotion is declining. And any sales that are occurring are tied directly to the massive advertising, promotion and sampling expenses.

40. The bottom line is that Lilly cannot seriously claim irreparable harm where, as

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C. Any Remaining "Harms" Alleged By Lilly Are Either Unfounded, Pure Speculation Or Simply Not True.

41. Lilly also speculates about a number of other alleged harms. Notably, however, none of them is supported by any actual evidence, and many are just plain wrong (or, as noted above, clearly quantifiable).

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While I do not see how this affects customers' goodwill toward Lilly, I do note that Lilly's alleged harm here is REDACTED — again, can be quantified.

43. Lilly and its declarants attempt to exaggerate the potential damages and identify actions that Lilly may take as a result of reduced revenues.

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Strattera's market share continues to decline as physicians continue to abandon their use of the product.[20]

44.

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Quite the contrary, as noted above it is business as usual. Lilly has not altered its earnings guidance or any other business plans because of Strattera.

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[20] IMS Prescription data for fourth quarter of 2008 through the first quarter of 2010 continue to demonstrate a declining trend in physician prescribing of Strattera.
[21] Sims Decl. ¶ 32 (emphasis added).
[22] *See* Mason Decl. ¶ 32.
[23] Mason Decl. ¶¶ 29-30.

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Moreover, Lilly's speculation is flatly contradicted by its own CEO, who recently stated that Lilly "still expect[s] to generate sufficient cash flow in the coming years to fund research and development, make necessary capital investments and to pursue anticipated business development opportunities."[24]

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47. REDACTED

So any assertions of harm in this regard are grossly exaggerated, if not plain wrong.

48. REDACTED

It is my experience in over 39 years of pharmaceutical marketing that, unless you can derive additional benefits that are tangible from education and ongoing clinical studies, the monies spent in these categories are unnecessary. It is clear that the total prescription growth for Strattera is declining and the sales revenues have been managed by increasing price, not demand for the actual product.[27] Just one year after the initial marketing of Strattera[28] prescriptions peaked and began to decline. Now, more than seven

[24] Lilly Press Release, August 12, 2010, Spataro Decl. Ex. 2.
[25] Mason Decl. ¶ 31.
[26] Mason Decl. ¶ 25.
[27] Lilly 2009 Annual Report at 22, Spataro Decl. Ex. 5.
[28] FDA approved Strattera on November 26, 2002.

years later the prescriptions continue to decline and sales continue to be managed by pricing actions resulting in Strattera being the highest priced product in its category.

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Further, as evidenced by Strattera's disappointing performance, the medical community does not appear to have an unmet medical need in this area and certainly no need that Strattera filled, so the loss of clinical studies for Strattera would not appear to be viewed as a lost opportunity.

* * *

49. As I have set forth above, Lilly has not identified or proven any actual irreparable harm that it will suffer. And to the extent it has identified any harm at all, Lilly has failed to point to anything indicating that money damages could not redress its alleged harms, nor that the generic companies would be unable to pay Lilly damages if, in fact, the generic products enter the market and are later found to infringe a valid or enforceable claim of the '590 patent.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct.

Dated: August 17, 2010

Respectfully submitted,

Harry C. Boghigian